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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

MEHTA, ASHWIN D

ART UNIT

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1638

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Applicant No.	Applicant(s)	
	09/759,790	BENSON, DAVID L.	
	Examiner Ashwin Mehta	Art Unit 1638	
<i>-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --</i>			
Period for Reply			
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.			
<ul style="list-style-type: none"> - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). 			
Status			
1) <input checked="" type="checkbox"/> Responsive to communication(s) filed on <u>04 October 2002</u> . 2a) <input type="checkbox"/> This action is FINAL . 2b) <input checked="" type="checkbox"/> This action is non-final. 3) <input type="checkbox"/> Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.			
Disposition of Claims			
4) <input checked="" type="checkbox"/> Claim(s) <u>1-43</u> is/are pending in the application. 4a) Of the above claim(s) _____ is/are withdrawn from consideration. 5) <input checked="" type="checkbox"/> Claim(s) <u>1-5, 7 and 20</u> is/are allowed. 6) <input type="checkbox"/> Claim(s) <u>6,8-19 and 21-43</u> is/are rejected. 7) <input type="checkbox"/> Claim(s) _____ is/are objected to. 8) <input type="checkbox"/> Claim(s) _____ are subject to restriction and/or election requirement.			
Application Papers			
9) <input checked="" type="checkbox"/> The specification is objected to by the Examiner. 10) <input type="checkbox"/> The drawing(s) filed on _____ is/are: a) <input type="checkbox"/> accepted or b) <input type="checkbox"/> objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). 11) <input type="checkbox"/> The proposed drawing correction filed on _____ is: a) <input type="checkbox"/> approved b) <input type="checkbox"/> disapproved by the Examiner. If approved, corrected drawings are required in reply to this Office action. 12) <input type="checkbox"/> The oath or declaration is objected to by the Examiner.			
Priority under 35 U.S.C. §§ 119 and 120			
13) <input type="checkbox"/> Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) <input type="checkbox"/> All b) <input type="checkbox"/> Some * c) <input type="checkbox"/> None of: 1. <input type="checkbox"/> Certified copies of the priority documents have been received. 2. <input type="checkbox"/> Certified copies of the priority documents have been received in Application No. _____. 3. <input type="checkbox"/> Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 14) <input type="checkbox"/> Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application). a) <input type="checkbox"/> The translation of the foreign language provisional application has been received. 15) <input type="checkbox"/> Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.			
Attachment(s)			
1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.		4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____. 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) 6) <input type="checkbox"/> Other: _____.	

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. The objection to claims 6, 12, 16, 25, and 29 is withdrawn in light of the claim amendments.
3. The rejection of claims 1-32 under the judicially created doctrine of obviousness-type double patenting is withdrawn in light of the claim amendments.
4. The rejection of claims 1-32 under 35 U.S.C. 102(e)/103(a) is withdrawn in light of the claim amendments.

Specification

5. The specification remains objected to for containing blank lines on page 7. Applicants assert, in the paper received 04 October 2002, that the ATCC deposit of seed 34B97 will occur when a notice of allowable subject matter is issued (response, page 10, 3rd full paragraph). However, the blank lines on page 7 appear in place of missing accession numbers for the inbred parents of 34B97, not 34B97 itself.

Claim Rejections - 35 USC § 112

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6. Claims 11, 15, 19, 24, 28, 32 remain and claims ⁶~~8~~, 21, 33-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reasons of record stated in the Office action mailed 05 July 2002 under item 4. Applicant traverses the rejection in the paper filed 03 October 2002. Applicant's arguments were fully considered but were not found fully persuasive. The amendments to claims 10, 14, 18, 23, 27, and 31 have overcome the aspect of the rejection regarding improper antecedent basis, and Applicant's assurance that the ATCC deposit number will be inserted upon notice of allowable subject matter overcomes the rejection regarding the term "34B97" for claims 1-32.

Regarding the indefinite issue concerning the relative terms in claims 11, 15, 19, 24, 28, and 32: Applicant argues that each of the claims recites two requirements: that 34B97 be an ancestor of the plant, and that the claimed plant be "capable of expressing a combination of at least two 34B97 traits" selected from a Markush grouping (response, paragraph bridging pages 12-13). However, this issue was not raised in this rejection. Applicant also argues that the terminology of the adjectives is well known in the art and would be understood by one skilled in the art. Applicants also argue that it is against the policy of the patent statutes to bar patent protection for inventions that are incapable of precise definition, assert that the terms in the claims are as precise as the subject matter of the invention permits (response, paragraph bridging pages 12-13 to page 13, 1st full paragraph). However, it remains unclear how one would differentiate, for example, "excellent" yield potential from "good" or "very good" yield potential. It is not clear if a plant that has good yield potential and good test weight, for example, would be encompassed by the claims.

In claim 6: there is improper antecedent basis for “protoplasts” in line 1. It is suggested that the term be removed from the claim, and that a new claim be introduced directed towards protoplasts produced from the tissue culture of claim 5.

In claims 8 and 21: the recitation “has been manipulated to be male sterile” renders the claims indefinite. It is not clear if the claim is directed towards detasseled plants, or plants that have been transformed with a gene conferring male sterility. The following amendments are suggested: 1) in claims 8 and 21, replace “manipulated to be male sterile” with --detasseled--; 2) add a new claim 44 directed towards a method of producing a male sterile maize plant comprising transforming the maize plant of claim 2 or 20 with a transgene that confers male sterility, and a new claim 45 directed towards a transgenic male-sterile maize plant produced by the method of claim 44.

In claims 34, 36 and 39: the recitation “34B97” renders the claims, and those dependent thereon, indefinite. Regarding indefiniteness of the term “34B97,” Applicant argues that one ordinarily skilled in the art would understand that this designation is drawn to a new and distinct hybrid maize seed with the designation of 34B97 and the morphological and physiological traits that are disclosed in the specification. Applicant asserts that the use of such a designation is common practice with the art (response, page 12, 2nd full paragraph). However, the morphological and physiological traits listed in the specification for seed 34B97 do not cover all of the traits of this plant line. For example, Table 1 does not report the resistance of 34B97 to many diseases and insects. If a corn plant displays all of the morphological and physiological traits as those reported for 34B97, but also displays a disease rating of 9 against southern rust, for example, can such a corn plant still be referred to as “34B97?” Further, the designation can be

changed. Amending claims 34, 36 and 39 to indicate that seed of 34B97 was deposited under ATCC Accession No. _____ will overcome the rejection.

New claims 33 and 34 refer to two other corn lines, “GE533003 and GE567919.” No morphological and physiological descriptions are provided at all for these two lines, and it is not clear what plants are referred to by these designations.

In claim 36: the recitation “desirable morphological and physiological traits” in line 6 renders the claim indefinite. It is not clear what traits one is to consider desirable versus undesirable.

In claim 37: the claim recites the recitation “the pedigree” in lines 1-2. There is insufficient antecedent basis in the claim and the claim from which it depends for this limitation.

In claim 40: the recitation “said population, on average, deriving at least 50% of its ancestral alleles” in line 2 renders the claim indefinite. It is not clear whether or not the all of the claimed plants have at least 50% of the ancestral alleles from 34B97. The metes and bounds of the claim are not clear.

In claim 42: the recitation “further comprising applying double haploid methods” renders the claim indefinite. The recitation broadens the scope of parent claim 39, which only involves crosses and does not encompass any double haploid method. It is also not clear what double haploid method is being referred to.

In claim 43: the recitation “a second plant” in line 9 renders the claim indefinite. It is not clear if this second plant is different from or the same as the “second plant” mentioned in line 6.

7. Claims 11-19, 24-32 remain and claims 9, 10, 22, 23, 33-43 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reason of record stated in the Office action mailed 05 July 2002 under item 5. Applicant traverses the rejection in the paper filed 04 October 2002. Applicant's arguments were fully considered but were not found fully persuasive.

Applicants argue that the claim amendments overcome the rejection for claims 8 and 21 (response, page 14, last full paragraph). The amendments overcome the written description issue raised for these claims, and the rejection is withdrawn from claims 8 and 21.

Applicants argue that the claims have been amended by adding the threshold, having 50% of the ancestral alleles, that limits the variation permitted among the genus, as well as an assayable function, capable of expressing a combination of at least two traits of 34B97.

Applicants argue that in plants, identifying characteristics are those detectable in the phenotype which are manifested through gene expression, and that claims to a particular species of invention are adequately described if the disclosure of relevant identifying characteristics are present in the application. Applicants argue that one of ordinary skill is reasonably apprised in knowing that a plant crossed with 34B97 will result in a plant having half the genetic contribution of 34B97, and that a further limitation set is that the plants must be capable of expressing a combination of at least two phenotypic characteristics of 34B97 (response, paragraph bridging pages 15-16). However, the specification does not provide a description of the alleles of 34B97, nor does it describe the functions that are associated with each of the alleles

of 34B97. The specification does not describe the alleles that govern the expression of any of the traits enumerated in the claims. As the alleles of 34B97 are not described, neither are the alleles of its descendants. Further, new claims 37, 40, and 41 encompass plants that can express any traits, none of which are described.

Applicants also argue that the specification supplies an extensive definition and description of “transgene” and transgenes of interest. Applicants argue that the trivial modification introduced by the transgenes to 34B97 are clearly supported and described in the present application (response, page 16, 1st full paragraph to page 17, 1st full paragraph). However, as written, the claims encompass any and all transgenes, even those that have yet to be isolated. Further, the effect that a transgene can have on its host plant depends on the function of its encoded product, among other considerations, and the modification cannot simply be described as “trivial.” A transgene that is a transcription factor, for example, could effect the expression of numerous genes and phenotypes. It is suggested that claims 12 and 25 be amended by listing the types of transgenes that may be introduced, provided that the specification or the prior art indicates that the gene has been isolated, for example genes that confer resistance to a plant virus.

Further, the specification does not provide any description of a method of making inbred plants “GE533003 and “GE567919” from 34B97 and for double haploid breeding and other double haploid methods. The specification at page 7 indicates crossing proprietary inbred plants GE533003 and GE567919 produced that plant 34B97, but makes no mention of producing these same inbreds from 34B97. The specification does not provide any description of these inbred plants at all.

8. Claims 33-35 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the reasons of record stated in the Office action mailed 05 July 2002 under item 6 for claims 1-32. Applicant traverses the rejection in the paper filed 04 October 2002. Applicant's arguments have been fully considered and found persuasive for claims 1-32. However, Applicant's arguments were not persuasive for new claims 33-43.

The claims are broadly drawn towards a method of making a hybrid plant designated 34B97 comprising crossing inbred maize plants GE533003 and GE567919; a method of making inbred plant GE533003 or GE567919 from hybrid maize plant 34B97.

Applicants have provided assurance that the seed of hybrid 34B97 will be deposited with the ATCC, and that the application will be amended to recite the assigned ATCC accession number, upon receipt of a notice of allowance (response, page 10, 3rd full paragraph). The rejection of claims 1-32 is therefore withdrawn in light of this assurance, and in accordance with MPEP 2411.02.

However, lines GE533003 and GE567919 are essential to the practice of claims 33-35. These two lines do not appear to be readily available to the public, as they are proprietary lines. The rejection is applied to claims 33-35.

9. Claims 34 and 35 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the

art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are broadly drawn towards a method of making an inbred plant comprising obtaining a hybrid maize plant 34B97 and generating from said plant a parental inbred parent line selected from the group consisting of GE533003 and GE567919; or wherein said generating step comprises using double-haploid breeding.

The specification provides a general discussion on the breeding, and asserts that the objective of commercial maize hybrid line development is to develop new inbred lines to produce hybrids that combine to produce high grain yields and superior agronomic performance (pages 3-7). However, the specification does not teach that hybrid maize plant 34B97 is to be used to produce its own inbred parents. The specification does not provide any guidance concerning how one skilled in the art is to practice the claimed method, even by using double haploid breeding. This method of producing inbred lines from hybrid plant varieties does not allow one to pick out the alleles that would be present in the resulting inbred line. Snape, J.W. (Doubled haploid breeding: theoretical basis and practical applications, In Review of Advances in Plant Biotechnology, 1989, A. Mujeeb-Kazi and L.A. Sitch, editors, International Maize and Wheat Improvement Center, Mexico, pages 19-29), for example, teaches that a completely random sample of gametes is fixed in this method, and that large populations of doubled haploid lines would be required to identify lines advancing even a single character (pages 23-24). Undue experimentation would clearly be required by one skilled in the art to produce a line comprising particular alleles at each and every locus. Further, the specification does not teach any molecular, morphological, and physiological characteristics of proprietary lines GE533003 and

GE567919. In the absence of this information, one skilled in the art would not even know how to identify these two lines. Given the breadth of the claims, unpredictability of the art and lack of guidance of the specification, undue experimentation would be required by one skilled in the art to make and use the claimed invention.

10. Claims 11, 15, 19, 24, 28, 32, 40, and 41 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are broadly drawn towards maize plants or its parts wherein at least one ancestor is 34B97, and has derived at least 50% of its ancestral alleles from 34B97 and is capable of expressing a combination of at least two 34B97 traits listed in those claims; or wherein the maize plant is derived from 34B97 transformed with one or more transgenes or 34B97 contains one or more genes transferred by backcrossing; or a population of 34B97 progeny hybrid maize plants, said population, on average, deriving at least 50% of its ancestral alleles from 34B97 and expressing any traits.

The specification teaches morphological and physiological characteristics of maize plant 34B97 (pages 17-34).

However, the specification does not teach how one may determine that a descendent of 34B97, that expresses at least 2 of the traits listed in claim 11 for example, or any traits, could determine that at least 50% of its alleles were derived from 34B97, if any of its other ancestors also expressed those traits. The specification does not teach any determinants, such as molecular

markers, that are unique to 34B97 and linked to the alleles that govern the traits, that one skilled in the art would need in order to determine that the traits could only have been derived from 34B97. Further, the specification does not teach the genes that govern the traits. It is not clear how one can determine that the traits could only have been derived from 34B97, or how one can distinguish 34B97 alleles versus those of other corn plants, if the specification does not teach the genes that govern the expression of those traits and unique molecular determinants associated with them, so that one can determine that it was inherited from 34B97. If other ancestors of the claimed plant also expressed the traits, then the genes governing the traits could have been inherited from that ancestor(s). If one does not know if a corn plant has 34B97 as an ancestor, and if unique molecular determinants that can identify genomic nucleic acid of 34B97 are unknown, undue experimentation would be required by one skilled in the art to alleles derived from 34B97. See Genentech, Inc. V. Novo Nordisk, A/S, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that “the specification, not the knowledge of one skilled in the art” must supply the enabling aspects of the invention. Given the breadth of the claim, unpredictability of the art and lack of guidance of the specification as discussed above, undue experimentation would be required by one skilled in the art to make and use the claimed invention.

11. Claims 1-5, 7 and 20 are allowed. Claims 6, 8-19 and 21-43 are rejected.

Contact Information

Any inquiry concerning this or earlier communications from the examiner should be directed to Ashwin Mehta, whose telephone number is 703-306-4540. The examiner can

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normally be reached on Mondays-Thursdays and alternate Fridays from 8:00 A.M to 5:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 and 703-872-9306 for regular communications and 703-872-9307 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

December 7, 2002


ASHWIN D. MEHTA, PH.D
PATENT EXAMINER